REMARKS

Reconsideration of this application, as amended, is respectfully requested.

I. Status of the claims

Claims 1-29, 67-77, 79, and 122-124 were pending in this case. Claims 4, 5, and 13-15 were withdrawn as being directed to non-elected inventions. New claim 125 has been added. This new claim is supported by claims 1 and 29. Accordingly, no new matter has been introduced into the application as a result of the present amendment.

Consideration and entry of this response is respectfully requested. The Applicants believe that response places this application into condition for an allowance or in better form for consideration on appeal. The response does not create any new issues that would require that any burdensome search be performed by the Examiner.

II. Rejections under 35 U.S.C. § 103 based on Chu and Shultz

Claims 1-3, 6-12, 16-28, 67-77, 79, and 122-124 were again rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu et al. U.S. Patent no. 6,174,704 ("Chu") in view of Shultz U.S. Patent no. 6,242,235 ("Shultz"). The basis for the rejection is described on pages 3 and 8. Applicants respectfully traverse this rejection.

Specifically, the Examiner states that Chu teaches compositions comprising aqueous solutions of alkylglycoside or alkylthioglycoside in amounts ranging from 0.5 to 5% w/v; that buffers such as TRIS or HEPES can be used to maintain a 7-8 pH value; that lysozyme can be included in the solutions; that the solutions can be used to prepare, extract, detect, purify and collect isolated proteins; that protein products can be incubated nickel charged resins and purified on resins; that the aqueous solutions may be used for lysing cells in a protein extraction process; and that octylthioglucosides can release proteins from cell membranes or cell walls. See pages 4 and 5 of the Office action. The Examiner then goes on to detail what is missing in Chu, namely the disclosure of inclusion of cationic surfactants comprising ethoxylated amine such as Tomah E-18-15 or Tomah E-18-5. The Examiner then uses Schulz to create the claimed method from the prior art.

Chu merely relates to lysis of host cells and extracting proteins of interest therefrom. See abstract. Specifically, Chu employs a reagent solution consisting essentially of an alkylglycoside or alkylthioglycoside. See col. 1, lines 51-55. Contrary to the Examiner's position, there is no teaching or suggestion in Chu that any protein stabilization is necessary or even desirable to do. Indeed, Chu is completely silent with respect to a composition having "at least one surfactant having a hydrophobic-lipophilic balance value in the range from about 11 to about 16" and further in combination with "at least one cell membrane altering compound." See claims 1 and 67. A disclosure of a solution consisting essentially of alkylglycoside or alkylthioglycoside with added buffers and/or lysosyme is not a disclosure or suggestion of the composition and method as presently claimed. Shultz adds nothing that remedies the deficiencies in Chu's teachings.

Shultz merely relates to compositions for stabilizing proteins. Shultz does not teach or suggest that detergents of any type in the HLB range of about 11-16 and he is limited to cationic surfactants. There would be no incentive to select ANY surfactant in this HLB range in order to provide the composition or method of the present invention as presently claimed. Moreover, Shultz does not actually teach or suggest cell lysis nor does he teach or suggest that this would be necessary or desirable to do.

Selection of a material such as a surfactant to provide enzyme stability does not automatically presume that it will also provide effective lysis. Some surfactants can form micelles that may act to provide additional stabilization of cellular membrane proteins, thus making extraction more difficult. Accordingly, without a suggestion of lysis in Shultz, one of ordinary skill would not be motivated by Shultz's teachings concerning protein stabilization to include a surfactant (e.g., Tomah E-18-15 or E-18-5) in Chu's lysis reagent and thus arrive with the presently claimed invention with any reasonable expectation of success.

It appears that the Examiner has simply used the Applicant's disclosure and claims as a blueprint. This is apparent since there is no motivation in the art to combine the references in the cited manner, and none is actually cited. For example, to motivate the combination of Chu and Shultz, the Examiner states that by adding a cationic surfactant such as Tomah E-18-15 or Tomah E-18-5, one would obtain the claimed composition. Well, yes they would, as evidenced by applicant's disclosure. But again, the art nowhere tells one of skill in the art to make that

combination. The Examiner's statements regarding the asserted combination is simply an assertion that a method and composition according to applicant's claims and specification will perform as advertised. There is no actual motivation in the art, and none is cited, to in fact make the asserted combination based on Chu and Shultz.

This is the hindsight trap, wherein pieces of prior art are simply strapped together to match whatever is claimed. It is improper, it violates the law and the Federal Circuit has condemned this approach. Why is it improper? Because it is empty and can be used to cobble together any invention. The Examiner falls into exactly the same trap. Chu relates to cell lysis in a protein extraction process but provides no teaching or suggestion that additional protein stabilization is desirable or even necessary to do. Thus, Chu fails to teach a protein stabilization agent so the Examiner finds a reference that does teach such a stabilization agent and simply states that if we combine this with Chu, voila, Chu's composition is now the claimed composition.

A §103 rejection based on a combination of references requires a ***motivation in the art***, not just a restatement of the beneficial result that was foretold by the applicant's disclosure and claims. Regarding the Examiner's hindsight approach, the Court of Appeals for the Federal Circuit has said the following:

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."
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> Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, **identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention.** Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.

In re Kotzab, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (citations omitted).

Thus, it is respectfully submitted that although the Examiner notes that combining elements to yield the invention would be beneficial, the Examiner does not actually cite any

motivation in the art to make that combination. Thus, applicants respectfully request favorable reconsideration of claims 1 and 67.

For the same reasons, applicants respectfully request favorable reconsideration of dependent claims 2-29, 68-77, 79, and 122-124. That is, the combinations used to reject the dependent claims have been created using the same logic. Moreover, since the dependent claims depend from either claim 1 or 67, they are patentable for the reasons stated above.

Accordingly, withdrawal of the § 103 rejection of the claims based on Shultz and Chu is in order and is respectfully requested.

IV. Conclusion

In light of the above discussion and amendment, the Applicants submit that the claims are in allowable condition. A Notice to this effect is respectfully requested.

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Examiner is invited to contact the undersigned representative if the Examiner believes this would be helpful in expediting the allowance of this application.

Respectfully submitted,

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